

REMARKS

The claims have been amended to put them in condition for allowance. The subject matter of the claims has been focused on the delivery of the vaccine in a *Listeria monocytogenes* carrier. This subject matter is supported by dependent claims 36 and 113, now cancelled.

In addition, claim 38 has been amended to recite that the patient remains tumor-free for at least 60 months. This is supported *inter alia* in Table 2 of the application as originally filed.

The Rejection of Claims 22-24, 26-38, 111, 113-115, 117-119, and 121 Under 35 U.S.C. §112, First Paragraph

Claims 22-24, 26-38, 111, 113-115, 117-119, and 121 stand rejected as lacking in enablement under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

The U.S. Patent and Trademark Office urges that the applicants have failed to provide any corroborating evidence demonstrating that the actual claimed method steps of the invention can be practiced both reproducibly and reliably in an animal model or in human pancreatic cancer with a DNA vaccine *per se*, such as a naked DNA, naked expression vector, or viral vector. See, e.g., Office Action, page 6, second full paragraph. The Office Action urges that the evidence of record relies on administering Listeria expressing mesothelin in the WF-3 mouse model or Listeria expressing mesothelin in humans with lung nodules, but not DNA-based therapy. Office Action at page 4, lines 17-18.

Applicants respectfully disagree with this characterization. For example, paragraphs 18 and 19 of the previously filed declaration by Elizabeth M. Jaffee, M.D. notes that Example 11 of the specification as filed describes the delivery of a DNA vaccine encoding mesothelin. This DNA construct was delivered as naked DNA attached to gold particles using a gene gun approach. As noted by Dr. Jaffee, this approach provided protection in the WF-3 tumor cell model, which Applicants have established is a useful model for studying ovarian cancer, mesothelioma, and pancreatic cancer.

Without agreeing with the characterization of the data submitted and its relationship to the previously pending claims, applicants have amended the claims so that they are commensurate in scope with the evidence which the U.S. Patent and Trademark Office acknowledges satisfies the enablement requirement, *i.e.*, the use of *Listeria* bacteria which express mesothelin. These amendments are made solely to advance prosecution. Applicants reserve the right to pursue subject matter no longer claimed in one or more continuation applications .

It is respectfully submitted that the present claims satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Allowance of all claims is now respectfully requested.

Respectfully submitted,

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